

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Hassan Mostafavi

Application No. 10/664,213

Filed: September 16, 2003

For: **LOCALIZATION OF A TARGET USING
IN VIVO MARKERS**

Examiner: Jonathan Cwern

Group Art Unit: 3737

Confirmation No. 3361

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed July 13, 2010 and in advance of the filing of an Appeal Brief, the Applicants respectfully request reconsideration of rejected claims 1, 3, 5-16, 49, 51-58, 62-79, and 81-89 in view of the following remarks.

DISCUSSION

In the current Office Action, mailed July 13, 2010 (the "Office Action"), the Patent Office rejects independent claims 1, 49 and 54 under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2002/0193685 to Mate et al. (Mate) in view of U.S. Publication No. 2002/0065461 to Cosman (Cosman) and further in view of U.S. Patent Pub. No. 2003/0007601 to Jaffray et al. (Jaffray). Dependent claims 3, 5-16, 51-53, 55-58, 62-79 and 81-89 were rejected over the same references as their base claims and one or more additional references.

Applicants respectfully disagree with the rejection of claim 1 because the references do not properly teach the limitations of claim 1.

The Office Action appears to rely upon a on motivation of adding the imaging mode of Cosman to the imaging mode of Mate in order to provide the first and second imaging modalities claimed; and then not using the imaging mode taught by Mate, which requires RF excitable markers (see page 4, final paragraph through page 5, first paragraph of the current Office Action). Applicant believes this logic is unreasonable for at least the following reasons. After reading Mate and Cosman it seems unreasonable to imagine that a person would consider redundantly imaging using the RF-excitabile marker system of Mate in addition to the camera marker imaging system of Cosman, but then not using the RF-excitabile markers required by each embodiment of Mate, because the result is simply imaging using Cosman. Second, it is hard to imagine why a person would redundantly image by using the imaging system of Cosman and then imaging again using the imaging system of Mate, other than only to read on Applicants claims.

The Office Action argues that Cosman does not rely upon camera imaged markers but provides for initial CT scanning at paragraph 64, and further refinement at paragraph 67 (see final paragraph of page 9 through first paragraph of page 10 of the Office Action). However, paragraph 64 requires camera imaged markers. Further, although refinement of x-ray imaging is described at paragraph 67, patient setup according to Cosman still requires camera imaged markers (see paragraph 65) prior to treatment (see paragraph 67). That is, the Office Action appears to consider only paragraph 67 of Cosman, out of context, without noticing that the entire purpose and policy of Cosman is to at least use external markers that can be imaged by a camera (see at least Figs. 1-3). Thus, the Office Action appears to not address Cosman as a whole, since Cosman requires camera imaged markers during both planning and treatment.

Similarly, the Office Action cites paragraph 74 of Mate (see lines 7-8 of page 5 of the current Office Action; and final paragraph of page 10 through first paragraph of page 11 of the Office Action), which only provides “boilerplate” type language regarding the claims. For example, paragraph 74 of Mate does not mention any specific monitoring system, apparatus, or method; or any limit of the claims. Consequently, Applicants respectfully request the Patent Office provide a reference in support of this Official Notice teaching the limits of the claims, in accordance with MPEP 2144.03.

Moreover, as stated in that paragraph, the claims and descriptions of Mate are still bound by the descriptions of “the specific embodiments disclosed in the specification” which all require excitable markers 30 (see Figs. 1-7). Moreover, it is well settled that a reference can only be used to teach subject matter set forth therein, and must be considered as a whole. Ironically, the Office Action attempts to then eviscerate this requirement by not using the RF-excitable marker imaging system of Mate, after adding the imaging system of Mate to Cosman (see final paragraph of page 4 through the first paragraph of page 5 of the current Office Action).

The citations of Cosman above also apply to why a practitioner would not attempt to combine the visible camera markers of Cosman with the kV or MV imaging of Jaffray (see paragraph 8), as argued in the Office Action (see second to last paragraph of page 4, third paragraph of page 11). That is, Cosman only describes imaging prior to treatment (paragraph 67 of Cosman only teaches that diagnostic X-rays from machines, or high energy X-rays for portal imaging can be used to visualize markers prior to treatment), while Jaffray is cited for treatment imaging. Thus, a practitioner would not add MV treatment imaging of Jaffray to pre-treatment imaging of Cosman since it would unnecessarily over-radiate the patient and does not provide any benefit (other than only reading on the claims; e.g., kV imaging is superior to MV imaging).

Next, to read on the first and second imaging modalities claimed, the Office Action cites a motivation of adding the imaging system of Cosman to the system of Mate, to “increase the accuracy of the alignment” (see lines 1-2 of page 5 of the Office Action). This adds the imaging system of Cosman to image redundantly what is already imaged in Mate purportedly to accomplish this. However, the Patent office (1) does not describe how using the two imaging systems will increase the accuracy of the alignment, (2) does not provide any evidence that redundantly imaging using those two systems will actually increase accuracy of alignment, and (3) does not describe how the two systems can be combined during planning and/or treatment.

For example, the Office Action has not sufficiently established that an “increase the accuracy of alignment” is recognized as a result effective variable. In establishing a result-effective variable, a particular parameter must first be recognized as a result-effective variable. See MPEP 2144.05. For example, in *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977), applicant claimed a wastewater treatment device having a particular tank volume to contractor area. *In re Antonie*, 559 F.2d 618. The prior art failed to recognize treatment capacity as a function of the tank

volume to contractor area ratio. *Id.* On this basis the court concluded the parameter optimized (i.e. treatment capacity) was not recognized in the art to be a result-effective variable. *Id.*

In addition, Applicants respectfully disagree that (e.g., other than based entirely on Applicants claims) any practitioner would find motivation for, or enabled embodiments of, a combination of the implanted excitable markers located with RF sensors of Mate (see Figs. 1-7) with the external, camera imaged markers of Cosman (see Figs. 1-3) or imaging of Jaffray (see paragraph 8). Clearly, it is not possible for these two types of markers to be combined into a single marker embodiment, as the implanted excitable marker of Mate is unable to satisfy the external camera visible marker of Cosman; and the external camera visible marker of Cosman is unable to be the implanted excitable marker located with an RF sensor of Mate. In fact, Mate teaches against using external non-excitable markers (see Mate paragraphs 7-8) by discouraging or otherwise criticizing the use of external non-excitable markers (see the end of paragraph 8) (Depuy Spine, Inc. v Medtronic Sofamor Danek, Inc. (CFAC Docket 2008-1240, -1253, -1401, decided June 1, 2009, page 14-15 (also see MPEP 2141.02 and 2143.01))).

Moreover, there is no benefit, use, or reason for the art to be taken in combination. Mate uses implanted excitable markers that are located with RF sensors, which can not sense non-excitable markers, such as the markers of Cosman. Conversely, Cosman teaches markers visible to a camera which can not sense optically invisible markers, such as the markers of Mate (Mate teaches against using external markers at paragraphs 7-8). The primary purpose of Mate is to image a target and markers 30 around the target so that during treatment, the markers can be excited with excitation source 32 to resonate at a low energy radial-frequency magnetic signal measurable from outside the body, in order to ensure proper positioning of the target (see Mate paragraphs 35-39 and 60-62). Thus, there is no use, benefit or motivation for a practitioner to add a second imaging modality to Mate. Moreover, a practitioner would not attempt to combine the external fiducial markers (e.g., markers 20, 21, 23 and 24) or implanted markers mentioned in Cosman (see Cosman paragraphs 31 and 67) with Mate because (1) Mate is not helped by surface mounted markers (see paragraphs 65-68) and (2) Mate is not helped by additional internal markers in addition to markers 30 (see Mate paragraphs 60-62). Thus, Applicants assert that the combination of Mate with Cosman is impermissible hindsight and is not enabled.

Moreover, the combination of Mate with Cosman would result in the anchored externally visible markers of Cosman combined with the RF sensors of Mate, which still doesn't disclose or suggest the claimed markers that are implanted completely internally to a body, and imaged using CT, and imaged using kV or MV imaging, as required by claim 1. That is, neither the implanted excitable markers of Mate, the camera visible markers of Cosman, nor the combination teach the above noted markers. Neither reference coordinates images from two different imaging modes.

In addition, by imaging markers wherein at least a plurality of the markers are residing completely internally in a body in two modalities, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kV and MV imaging, some embodiments described in the specification, for example, without limitation thereto, may provide one or more of: (1) the benefit of imaging in an x-ray imaging modality is an isocenter of an x-ray image system, and imaging in a second x-ray imaging modality using a high energy beam of radiation of a treatment machine (see paragraphs [0043], [0048] and [0055]-[0057] and [0074] of the Application; and claims 49 and 54); and (2) setting up a treatment plan using CT images of anatomy, tumor, and the markers; and then using kV and/or MV imaging to quickly, properly position a patient during treatment to ensure accurate placement of the tumor based on the imaged markers, for irradiating the tumor with the treatment beam (see at least paragraphs 53-54 of the Application; and claims 62-75 and 82-84; and new claims 88-89). However, the references do not contemplate or enable such benefits.

Arguments similar to those above apply to corresponding limitation of independent claims 1, 49 and 54, and dependent claims thereof. Thus, Applicants request that the Pre-Appeal Brief Conference Panel withdraw the rejection of the pending claims for at least the reasons stated above.

Respectfully submitted,

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Dated: 2/10/10-13

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2/10/10-13